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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,999	07/28/2003	Rudolf Edgar Falk	1719.007US2	7333

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EXAMINER	
MAIER, LEIGH C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,999	FALK ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *275-296* is/are pending in the application.

4a) Of the above claim(s) *275-283,287 and 289-296* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *284-286 and 288* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *9/9/05*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on July 15, 2005 is acknowledged. However, before the beginning of examination, Applicant's representative, Greg Butler, inquired about shifting the election to Group II. The examiner agreed to allow this shift. See attached interview summary.

The traversal is on the ground that examination of both groups would not constitute an undue burden. This is not found persuasive because the searches for the two inventions are not coextensive. The search for a method of use is not required for the search of the product.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 284-286 and 288 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that Applicant, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a combination of dosage amounts comprising hyaluronic acid (HA) having molecular weight of less than 750,000 daltons. Claims 284-286 are generic combinations wherein the first dosage amount comprises HA and an NSAID and/or a chemotherapeutic agent and, optionally, an antioxidant. The second dosage amount comprises HA and an anti-cancer drug and/or drug suitable for use to treat cancer. Claim 288 is drawn to a specific combination wherein the first dosage amount comprises HA (as sodium hyaluronate) and diclofenac sodium and/or novantrone and, optionally, vitamin C. The second dosage amount comprises HA (as sodium hyaluronate) and novantrone.

Throughout the specification, there are laundry lists of suggested pharmaceutical agents, but the examiner finds no particular support for either of the generic or specific combinations of therapeutic agents in the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 284-286 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 284, at line 11, recites "a chemotherapeutic agent" and at line 16, recites "an anti-cancer drug" or "drug suitable for use to treat cancer." Typically, a drug used to treat cancer is thought to be a "chemotherapeutic agent." However, the instant specification refers to "chemotherapeutic agents" and "anti-cancer drugs" in the alternative. It is not clear is one is a sub-set of the other or if each is a non-overlapping group. Furthermore, the examiner finds no

explanation regarding the difference between "an anti-cancer drug" and "a drug suitable for use to treat cancer." Due to these uncertainties, on of ordinary skill would not be apprised of the metes and bounds of the claims. The claims are thereby rendered vague and indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 284-286 are rejected under 35 U.S.C. 103(a) as being unpatentable over DELLA VALLE et al (US 5,166,331) in view of FRANCHI et al (Rec. Prog. Med., 1989 – abstract) and WOOD (US 4,912,136).

The invention is as set forth above.

DELLA VALLE teaches that HA (including salts) having molecular weight of about 500-730 kD has utility for preparing intra-articular injection dosages for the treatment of joint

disorders. See abstract; col 14 and lines 10-27. The reference specifically suggests that the HA is a suitable vehicle for a variety of pharmaceutical agents, including NSAIDs and chemotherapeutics. The reference does not exemplify the particularly recited dosages forms.

FRANCHI teaches the treatment of rheumatoid arthritis (RA) by intra-articular administration of methotrexate and orgotein (an antioxidant). See abstract.

WOOD teaches the use of an NSAID for conditions requiring immunosuppressive therapy, such as RA. See abstract and table in col 3.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare dosage amounts comprising any combination of these pharmaceutical agents having utility for the treatment of a joint disorder, such as RA. One of ordinary skill would reasonably expect success because DELLA VALLE had suggested the preparation of such compositions. It would be within the scope of the practitioner to prepare dosages with any combination, as needed, for the treatment of a patient in need, for the additive effects.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at http://**www.uspto.gov**. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more. Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

Leigh C. Maier

Leigh C. Maier
Primary Examiner
September 30, 2005